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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/528,488 | 03/17/2000 | Najla Guthrie | 52953.8 | 3790 |

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USDA, ARS, OTT
5601 SUNNYSIDE AVE
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BELTSVILLE, MD 20705-5131

EXAMINER

OWENS JR, HOWARD V

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1623

DATE MAILED: 09/09/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/528,488

Applicant(s)

GUTHRIE ET AL.

Examiner

Howard V Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 25
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 U.S.C. § 103

Claims 1-12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Cook et al., *Nutritional Biochemistry*, pp. 66-76, 1996 in combination with Robbins, U.S. Patent No. 3,867,541.

Claims 1-8 are drawn to a method of reducing the level of substances in a mammal which contribute to cardiovascular diseases or disorders comprising administering an effective amount of a polymethoxyflavone to reduce the production of substances in a mammal which contribute to cardiovascular diseases and/or disorders.

Claims 9-12 are drawn to polymethoxyflavone compositions suitable for reducing the level of substances in a mammal which contribute to cardiovascular diseases.

Cook teaches that there is a significant inverse association between dietary flavonoid intake and mortality from coronary heart disease (CHD) via administration of flavonoids such as polyhydroxyflavones. Cook also teaches that flavonoids act as inhibitors of low density lipoprotein (LDL) oxidation and platelet aggregation, two conditions that contribute to atherosclerosis or cardiovascular disease.

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Although Cook teaches flavones broadly as well as hydroxylated flavones, Cook does not specifically teach the use of methoxylated flavones, nor the specific methoxyflavones claimed.

Robbins bridges the nexus between the invention and the prior art as it teaches that the methoxylated flavonoid compositions such as sinensetin and limocitrin (see col. 11, lines 30- and column 4, lines 10-68) exhibit strong anti-adhesive effects on blood cells which may show clinically that they are useful as antithrombogenic agents (column 3, lines 25-30). Robbins teaches that the blood cell aggregation can cause infarction of vital organs (col.9, lines 4-15), which inherently teaches the use of these compounds in compositions for the treatment of coronary artery disease and supports the use of the methoxylated form of flavones.

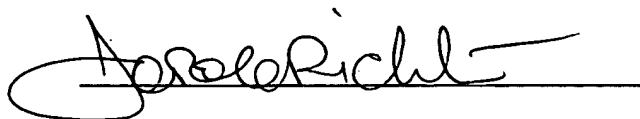
Applicant has set forth compositions wherein known polymethoxyflavones are combined for reducing the level of substances which contribute to cardiovascular diseases or disorders. The combination of two compounds known to achieve the same effect in a composition is seen as obvious, unless there is some unexpected result. The prior art has clearly set forth the blood cell anti-adhesive/ anti-aggregate, quality of methoxylated flavonoids (having at least two methoxyl substituents) such as sinensetin and limocitrin.

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention was made to use a polymethoxyflavones in a composition for reducing the level of substances that contribute to cardiovascular diseases or disorders.

A person of ordinary skill in the art would have been motivated to use polymethoxyflavones in a composition for reducing the level of substances that contribute to cardiovascular diseases or disorders given that the prior art has set forth that flavones, specifically polyhydroxy or polymethoxyflavones can act as inhibitors of substances which contribute to CHD, such as LDL oxidation and platelet aggregation. It is *prima facie* obvious to combine two compounds each of which is taught by prior art to be useful for same purpose in order to form a composition that is to be used for very same purpose.

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Howard V. Owens
Patent Examiner
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A handwritten signature in black ink, appearing to read "Johann Richter", is written over a horizontal line.

Johann Richter, Ph.D., Esq.
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (703) 306-4538 . The examiner can normally be reached on Tue.-Fri. from 8:30 a.m. to 7 p.m.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for this Group is (703) 308-4556.